AMENDMENTS TO THE CLAIMS

50. – 66. (Cancelled)

67. (New) A process for the preparation of a concentrated, sterile injectable solution containing docetaxel comprising the following steps:

a) obtaining an anhydrous form of docetaxel in which the water content is lower than 0.12% w/w, by the substeps:

a)(i) the hydrated docetaxel, in a solvent or in a chemically inert solvent mixture that forms an azeotrope with water and is of sufficient polarity to effect complete solubilization of the docetaxel, said solvent being selected from the group consisting of linear or branched alcohols, organic acids, halogenated solvents, and an aromatic solvent;

a)(ii) removing the water of hydration contained in the mixture (i) by azeotropic distillation at a temperature between -20 and 40°C and at a pressure between <0.001 and 780 mm Hg, preferably, between 1.0 and 20.0 mm Hg, until the water content is lower than 0.12% w/w;

b) adding an acid, selected from the group consisting of ascorbic acid, citric acid and acetic acid, as a stabilizing agent, to polysorbate 80, under an atmosphere of nitrogen, in a sufficient quantity to adjust the pH in the range of 3.0 to 6.5;

c) slowly adding amorphous solid docetaxel, obtained by steps described in a)(i) and a)(ii) and that is free of ethanol, to the resulting solution of the step (B), under agitation and a nitrogen atmosphere, until the docetaxel is completely solubilized and a transparent solution is formed, in which the concentration of the docetaxel in its anhydrous form in the polysorbate 80, is in the range from 11 to 100 mg/ml; and

d) filtering the concentrated solution obtained in c) by passage through a sterilizing membrane having a porosity less than or equal to 0.45 μm, to obtain a concentrated, sterile injectable solution of docetaxel.

68. (New) The process according to claim 67 wherein an anhydrous solvent or a mixture of solvents is used in steps a)(i) and a)(ii).

69. (New) The process according to claim 67 wherein the solvents employed in the steps a)(i) and a)(ii) are a short chain linear or branched alcohol; a halogenated solvent or an aromatic solvent.

70. (New) The process according to claim 69 wherein the solvent employed is a short chain linear or branched alcohol.

71. (New) The process according to claim 70 wherein the alcohol employed is ethanol.

72. (New) The process according to claim 67 where in the step a), the starting docetaxel form contains 0.13 to 6.27% w/w of water, the solvents employed in the steps a)(i) and a(ii) are absolute ethanol and anhydrous toluene in a relative proportion of 1:9, and step a)(ii) is performed at a pressure between <0.001 and 100 mm Hg.

73. (New) The process according to claim 67 wherein the docetaxel employed as raw material in step a) is (2R,3S) 4-acetoxy-2-α-benzoyloxy-5β-20-epoxy-1,7-β-10-β-tri-hydroxy-9-oxo-tax-11-en-13α-yl 3-tert-butoxycarbonylamino-2-hydroxy-3-phenylpropionate, in its hydrated form, in which the amount of hydration water is 0.13 to 6.27% w/w.

74. (New) The process according to claim 67 wherein the docetaxel employed as the raw material in step a) is (2R,3S) 4-acetoxy-2-α-benzoyloxy-5β-20-epoxy-1,7-β-10-β-tri-hydroxy-9-oxo-tax-11-en-13α-yl 3-tert-butoxycarbonylamino-2-hydroxy-3-phenylpropionate •3 H_20, in which the amount of hydration water is 6.27% w/w.

75. (New) The process according to claim 67 wherein the docetaxel obtained at the end of the step a) is (2R,3S) 4-acetoxy-2-α-benzoyloxy-5β-20-epoxy-1,7-β-10-β-tri-hydroxy-9-oxo-tax-11-en-13α-yl 3-tert-butoxycarbonylamino-2-hydroxy-3-phenylpropionate, in which the water content is in the range of 0.00 to 0.12% w/w.

76. (New) A process according to claim 67 wherein the final concentration obtained in the concentrated solution containing (2R,3S) 4-acetoxy-2-α-benzoyloxy-5β-20-epoxy-1,7-β-10-β-trihydroxy-9-oxo-tax-11-en-13α-yl 3-tert-butoxycarbonylamino-2-hydroxy-3-phenylpropionate, docetaxel, is from 1 to 100 mg of the active principle, on an anhydrous basis, for each mL of the polysorbate 80.

77. (New) The process according claim 67 wherein the acid stabilizing agent is added to the polysorbate 80 in an amount effective to adjust the pH of the pharmaceutical formulation in the range from 3.0 to 4.5.

78. (New) The process according claim 67 wherein the stabilizing agent is ascorbic acid.

79. (New) The process according claim 77 wherein the stabilizing agent is ascorbic acid.